



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Biomet Manufacturing Corporation
Ms. Patricia S. Beres
Senior Regulatory Affairs Specialist
P.O. Box 57
56 East Bell Drive
Warsaw, Indiana 46581

May 15, 2015

Re: K150424

Trade/Device Name: JuggerStitch Meniscal Repair Device

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II

Product Code: MBI

Dated: February 17, 2015

Received: February 19, 2015

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (*if known*)

K150424

Device Name

JuggerStitch Meniscal Repair Device

Indications for Use (Describe)

The JuggerStitch Meniscal Repair Device is indicated for repair of vertical longitudinal full thickness tears (i.e. bucket-handle) in the red-red and red-white zones. These devices are not to be used for meniscal tears in the avascular zone of the meniscus.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the JuggerStitch Meniscal Repair Device 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact: Patricia S. Beres
Senior Regulatory Affairs Specialist

Date: February 17, 2015

Subject Device: Trade Name: JuggerStitch Meniscal Repair Device
Common Name: Soft Tissue Fixation Device
Classification Name:
• MBI– Fastener, Fixation, Nondegradable, Soft Tissue (Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040)

Legally marketed devices to which substantial equivalence is claimed:

- MaxFire MarXmen Meniscal Repair Device (K111564)

Device Description

The JuggerStitch Meniscal Repair Device is a permanent fixation anchor system comprised of UHMWPE suture, with two non-resorbable polyester sleeves. The device comes as a unit, pre-assembled on either a straight or curved inserter.

Intended Use and Indications for Use

The JuggerStitch Meniscal Repair device is indicated for repair of vertical longitudinal full thickness tears (i.e. bucket-handle) in the red-red and red-white zones. These devices are not to be used for meniscal tears in the avascular zone of the meniscus.

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing, and indications) of the JuggerStitch Meniscal Repair Device are similar or identical to the predicate devices or other previously cleared devices.

The rationale for substantial equivalence is based on consideration of the following characteristics:



- **Intended Use:** The proposed JuggerStitch Meniscal Repair Device is intended for the repair of the vertical longitudinal full thickness tears (i.e. bucket-handle) in the red-red and red-white zones, which is identical to the intended use of the predicate device.
- **Materials:** The proposed JuggerStitch Meniscal Repair Device uses the same implant material as the predicate device.
- **Design Features:** The proposed JuggerStitch Meniscal Repair Device incorporates similar design features as the predicate device.
- **Sterilization:** The proposed JuggerStitch Meniscal Repair device is provided sterile via Ethylene Oxide (EtO), the same sterilization method utilized for the predicate device.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
 - Non-clinical laboratory testing was performed to verify the fixation strength of the JuggerStitch Meniscal Repair Device in mechanical testing as compared to the MaxFire MarXmen Meniscal Repair Device. The test results indicate that the JuggerStitch Meniscal Repair Device provides equivalent fixation strength to the predicate device and would be functional within their intended use.
- Clinical Tests
 - None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

The proposed JuggerStitch Meniscal Repair Device has similar intended use, technology characteristics, and mechanical performance as the predicate devices. The performance testing data identified no new risks and substantial equivalence to the legally marketed predicate devices.